10/534082 STATES PATENT AND

Application No.:

Based on PCT/JP2003/014138

Filed:

Intl. Filing 06 NOVEMBER 2003

1st Inventor:

Shuji HINUMA

For:

Novel FPRL1 Ligands and Use Thereof

Atty. Dkt. No.

3118 US0P

Art Unit:

tba

Examiner:

Allowed:

Batch:

Information Disclosure Statement

MAIL STOP PCT P.O. Box 1450 Commissioner for Patents Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §1.56, 1.97 and 1.98, Applicants request consideration of the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B. A legible copy of each listed reference is herewith being provided to the Examiner.

This Information Disclosure Statement is being submitted within 3 months of the filing date of the above-identified application, and before the mailing date of the first Office Action on the merits, thus, no certification or fee is required.

Applicants respectfully request that the listed documents be considered by the Examiner and formally be made of record in the present application and that an initialed copy of the attached form PTO/SB/08A be returned in accordance with MPEP §609.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney.

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Respectfully submitted,

Mark Chao, Ph.D., Reg. No. 37,293

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PTO/SB/08A (08-03)

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Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (I known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	A1	WO 03/106683 A1 - Abstract only	12/24/2003	Takeda Chemical Industries		
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				Application Number	Based on PC1/JP2003/014138		
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STATEMENT BY APPLICANT				First Named Inventor	Shuji HINUMA		
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Sheet	2	of	3	Attorney Docket Number	3118 US0P		

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	_
Initials*	No. ¹	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	A3	P.M. MURPHY, et al., "A Structural Homologue of the N-Formyl Peptide Receptor", The Journal of Biological Chemistry, (1992), pp. 7637-7643, Vol. 267, No. 11.	
	A4	Y. LE, et al., "Receptors for Chemotactic Formyl Peptides as Pharmacological Targets", International Immunopharmacology, (2002), pp. 1-13, Vol. 2.	
	A5	Y. LE, et al., "Amyloid Beta42 Activates a G-Protein-Coupled Chemoattractant Receptor, FPR-Like-1", The Journal of Neuroscience, (2001), RC123, 1 of 5, Vol. 21.	
<u>, , , , , , , , , , , , , , , , , , , </u>	A6	H. YAZAWA, et al., "Beta Amyloid Peptide (AlphaBeta42) is Internalized via the G-Protein-Coupled Receptor FLPL1 and Forms Fibrillar Aggregates in Macrophages", The FASEB Journal, (2001), pp. 2454-2462, Vol. 15.	
	A7	T. CHRISTOPHE, et al., "The Synthethetic Peptide Trp-Lys-Tyr-Met-NH2 Specifically Activates Neutrophils", The Journal of Biological Chemistry, (2001), pp. 21585-21593, Vol. 276, No. 24.	
	A8	A. BETTEN, et al., "A Proinflammatory Peptide fro Helicobacter Pylori Activates Monocytes to Induce Lymphocyte Dysfunction and Apoptosis", The Journal of Clinical Investigation, (2001), pp. 1221-1228, Vol. 108, No. 8.	
	A9	DE YANG, et al., "Human Dendritic Cells Express Functional Formyl Peptide Receptor-Like-2 (FPRL2) Throughout Maturation", Journal of Leukocyte Biology, (2002), pp. 598-607, Vol. 72.	
	A10	M. PERRETTI, et al., "Endogenous Lipid-and Peptide-Derviced Anti-Inflammatory Pathways Generated with Glucocorticoid and Aspirin Treatment Activate the Lipoxin A4 Receptor", Nature Medicine, (2002), pp. 1296-1302, Vol. 8, No. 11.	
	A11	Y. CUI, et al., "Potential Role of the Formyl Peptide Receptor-Like 1 (FPRL 1) in Inflammatory Aspects of Alzheimer's Disease", Journal of Leukocyte Biology, (2002), pp. 628-635, Vol. 72	
	A12	S.M. SHAWAR, et al., "Peptides From the Amino-Terminus of Mouse Mitochondrially Encoded NADH Dehydrogenase Subunit 1 are Potent Chemoattractants", Biochemical and Biophysical Research Communications, (1995), pp. 812-818, Vol. 211, No. 3.	

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	A13	H. CARP, "Mitochondrial N-Formylmethionyl Proteins as Chemoattractants for Neutrophils", J. Exp. Med., (1982), pp. 264-275, Vol. 155.	
	A14	S. ANDERSON, et al., "Sequence and Organization of the Human Mitochondrial Genome", Nature, (1981), pp. 457-465, Vol. 290.	
	A15	Y. LE, et al., "Formyl-Peptide Receptors Revisited", Trends in Immunology, (2002), pp. 541-548, Vol. 23, No. 11.	
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